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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/511,827

10/20/2004

Hartmut Klocke

KLOCKE2

8558

1444 7590 01/22/2009  
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EXAMINER

ALEXANDER, LYLE

ART UNIT

PAPER NUMBER

1797

MAIL DATE

DELIVERY MODE

01/22/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/511,827	<b>Applicant(s)</b> KLOCKE, HARTMUT	
	<b>Examiner</b> Lyle A. Alexander	<b>Art Unit</b> 1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 06 November 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 16-20, 23-31 and 33-36 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 16-20, 23-31 and 33-36 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

In light of the 11/6/08 amendments, a further search was made and new a reference has been found.

***Claim Rejections - 35 USC § 102***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 16-19, 23-26, 28-31, 33, 35 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Steinbrink (USP 4,078,892).

Steinbrink teach a kit for the determination of bilirubin in blood. Column 2 lines 6+ teach the kit(10) comprises flexible walled, hermetically sealed reagent containers(14) that are packaged in a kit so that elements are conveniently available when needed. Hub(34) on the containers(14) is pierced by pipette(28) and permits transfer of the sample into the container(14). The hub(34) has also been read on the claimed "break away tip" and "adhesive film covering said inlet." Column 4 lines 43-51 teach the containers(14) have flexible walls(18) and are constructed from plastic materials, such as polyethylene or polypropylene. Further, capsule(20) contain reagent solution(22) and is within container(14). Figure 1 shows there are a series of contains to make colorimetric comparison and has been read on the claimed "information-carrying medium ... ". The Office has read the claimed "*reaction chamber*" on the taught **container(14)**; the claimed "*inlet*" on the taught **hub(34)** and the claimed "*indicator chamber*" on the taught **capsule(20)**.

***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 20,27, 34 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Steinbrink.

See Steinbrink *supra*.

Steinbrink are silent to the claimed litmus test strip of claim 20, the indicator or reaction in the form of a tablet of claim 27 and the at least two reaction chambers and/or two indicator chambers of claims 34 and 36.

The court decided In re Boesch (205 USPQ 215) that optimization of a result effective variable is ordinarily within the skill of the art. A result effective variable is one that has well known and predictable results. The choice of an indicator is a result effective variable having the well known and expected results of detecting the analyte of interest. Also, the physical state of an indicator or reaction is a result effective variable providing the well known and expected results of indication. Finally, the number of reaction chambers and/or indicator chambers is a result effective variable based upon the scale of analysis desired.

Litmus test strips are notoriously well known in the art for testing the pH of a solution and is advantageous because it is inexpensive and widely available. It would have been within the skill of the art to modify Steinbrink and use a litmus paper test strip to test the pH of the test solution to gain the above advantages and as optimization of a result effective variable.

It is notoriously well known in the art to provide an indicator or reactant in a dry state in the form of a tablet to gain the advantages of less weight for shipping, easier handling of the indicator or reagent in the form of a tablet and a longer shelf life. It would have been within the skill of the art to modify Steinbrink and provide the indicator or reactant in the form of a dry, tablet to gain the above advantages and as optimization of a result effective variable.

It is well known in the art to provide multiple chambers in a device so that plural samples and/or test can be conducted simultaneously which will shorten the time required for analysis. It would have been within the skill of the art to further modify Steinbrink and provide at least two reaction chambers and/or two indicator chambers to gain the above advantages and as optimization of a result effective variable.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lyle A. Alexander whose telephone number is 571-272-1254. The examiner can normally be reached on Monday, Tuesday and Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Lyle A Alexander  
Primary Examiner  
Art Unit 1797

/Lyle A Alexander/  
Primary Examiner, Art Unit 1797